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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Refer to: FEI 3002829541

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
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May 22, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Steven J. Garvin, Owner
I.S.P. Company, Inc.
RR4, Box 930
Salem, West Virginia 26426-8917

Dear Mr. Garvin:

On January 12, 2000, the Food and Drug Administration (FDA) conducted an inspection at your establishment located at RR4, Box 930, Salem, West Virginia. This letter is in reference to your firm's manufacture and distribution of "Garvin's Original I.S.P. SKIN CARE FOOT CARE OINTMENT." This product is a drug as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act), since its labeling represents the product as useful for treating various disease conditions in both man and animals.

The labeling for "I.S.P. Ointment" declares the active ingredients: "Iodine: antibacterial, antifungal; Sulfur: antifungal lubricant; Petrolatum: topical lubricant, skin protectant," and recommends the product for use as a "Soothing application for skin irritations, cuts, weak damaged nails, dry cracked hands and feet, vaginal and anal irritations." Based on its labeling and declared formulation, "I.S.P. Ointment" fails to comply with several final rules (Title 21, Code of Federal Regulations (CFR)) as follows:

1. The active ingredient, sulfur, is prohibited from use in any over-the-counter (OTC) antifungal drug product for human use (21 CFR 310.545(a)(22)(ii)), and is not permitted for use as an active ingredient in any OTC drug product offered as a skin protectant for use on humans without an approved new drug application (21 CFR 310.545(a)(18)(i)).

2. No antifungal active ingredient is permitted for use on the nails in the absence of an approved new drug application (21 CFR 310.545(a)(22)(iii)).

3. The active ingredient, iodine, is not included in the final rule for topical antifungal drug products for OTC human use as an active antifungal ingredient (21 CFR 333.210).

4. The final rule for topical antifungal drug products for OTC human use (21 CFR Part 333, Subpart C) prohibits any combination of two or more antifungal active ingredients in the absence of an approved new drug application.

5. The product is offered for use in treating anal irritations and fails to comply with the final rule for anorectal drug products for OTC human use (21 CFR Part 346).

"I.S.P. Ointment" is, therefore, a new drug without an approved new drug application (NDA) and, as such, may not be legally marketed in the United States under Section 505(a) of the Act. The product is also misbranded under Sections 502(f)(1) and (2) of the Act because it fails to bear adequate directions for use and warnings for safe use for the indications in the labeling, and such directions and warnings cannot be employed in the labeling of an unapproved new drug. The product is further misbranded under Section 502(a) of the Act because the labeling is misleading, in that, the product is not generally recognized as safe and effective as formulated and labeled. Our records do not indicate that I.S.P. Company, Inc. is registered as a drug manufacturer, nor is "I.S.P. Ointment" listed as a marketed drug product as required by Section 510 of the Act. Therefore, the product is further misbranded under Section 502(o) of the Act.

In addition to the violations previously mentioned in this Warning Letter pertaining to the human use of "I.S.P. Ointment," we have found additional violations with regards to its animal use.

Animal and human drugs are defined under Section 201(g)(1) of the Act as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure or function of the body of man or other animals. Unless an animal drug is generally recognized by qualified experts as safe and effective for its intended uses, it is a "new animal drug" under Section 201(v) of the Act. A "new animal drug" may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA).

Our review of the labeling of your "I.S.P. Ointment" reveals that it is a "new animal drug." We consider this drug to be adulterated within the meaning of Section 501(a)(5) of the Act, in that this is a new animal drug which is unsafe within the meaning of Section 512(a)(1)(A) of the Act. Under Section 512(a)(1)(A), a new animal drug is considered to be unsafe unless there is an approved NADA for the product. According to our records, you do not hold an NADA for this particular drug product.

In addition, during the inspection, our investigator documented deviations from the Current Good Manufacturing Practice Regulations (21 CFR Parts 210 & 211). These deviations cause "I.S.P. Ointment" to be adulterated within the meaning of Section 501(a)(2)(B) of the Act and include the following:

- Failure to test each lot of incoming drug components, containers, and finished product to determine conformance with appropriate specifications for identity and strength, prior to release;

- Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished;

- Failure to establish written procedures for the production and process control designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess, including, but not limited to, the validation of your manufacturing process and the establishment of finished drug product specifications;

- Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch;

- Failure to establish a written procedure describing the distribution of the drug product and to maintain a system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary;

- Failure to establish written procedures describing the testing program designed to assess the stability characteristics of the drug product that will be used in determining appropriate storage conditions and expiration dates; and

- Failure to establish a quality control unit.

The above deviations were listed on FDA Form 483 issued to you at the close of the inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. We request that you take prompt action to correct these violations. Failure to do so may result in enforcement action being initiated by the FDA without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of such products and for injunction against the manufacturer and/or distributor of such products.

It is necessary that you take immediate action on this matter. Please notify this office in writing, within 15 working days from the date you receive this letter, as to the specific steps you have taken or are taking to correct the noted violations and to prevent their recurrence, including the timeframe within which the corrections will be completed. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. If you have specific questions about the content of this letter, please feel free to contact Mr. MacIntire at (804) 379-1627, extension 14.

Sincerely,

Lee Bowers
Director, Baltimore District